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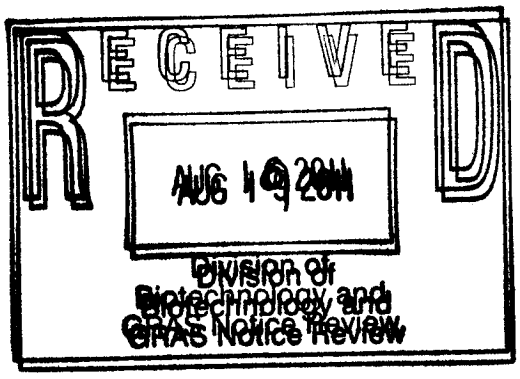

Notice to US Food and Drug Administration that *Bacillus coagulans* GBI-30, 6086, a Novel Probiotic, is Generally Recognized as Safe for use in Foods

Submitted by the Notifier:

Ganeden Biotech, Inc.
5915 Landerbrook Drive, Suite 304
Mayfield Heights, Ohio 44124

Prepared by the Agent of the Notifier:

AIBMR Life Sciences, Inc
4117 S Meridian
Puyallup WA 98373

August 11, 2011

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GRAS Exemption Claim

Ganeden Biotech, Inc. (the notifier), in consultation with an independent panel of experts qualified by scientific training and experience to evaluate the safety of ingredients intended for use in food, has determined that *Bacillus coagulans* GBI-30, 6086 is Generally Recognized as Safe (GRAS), consistent with section 201(s) of the Federal Food, Drug, and Cosmetic Act. This determination has been made based on scientific procedures. Therefore, the use *Bacillus coagulans* GBI-30, 6086 in foods is exempt from the requirement of pre-market approval.

(b) (6)

8/11/11

David Keller, DPM, MBA Date

Notifier

Name and Address of the Notifier

Notifier

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Vice President of Scientific Operations

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Common or Usual Name

Bacillus coagulans GBI-30, 6086 (GanedenBC^{30}™)

Conditions of Use

Bacillus coagulans GBI-30, 6086 is intended to be added to a wide variety of foods at levels up to approximately 2 x 10^9 CFUs per serving. The food categories as defined in 21CFR 170.3(n) to which *Bacillus coagulans* GBI-30, 6086 may be added include: Baked goods and baking mixes; alcoholic beverages; beverages and beverage bases; breakfast cereals; chewing gum; coffee and tea; condiments and relishes; confections and frostings; dairy product analogs; fats and oils; fruit juices; frozen dairy desserts and mixes; fruit and water ices; gelatins, puddings, and fillings; grain products and pastas; hard candy and cough drops; herbs, seeds, spices, seasonings, blends, extracts, and flavorings; jams and jellies; milk; milk products; nuts and nut products; plant protein products; processed fruits; processed vegetables and vegetable juices; snack foods; soft candy; soups and soup mixes*; sugar; and sweet sauces, toppings, and syrups.

**Bacillus coagulans* GBI-30, 6086 is not intended for use in any product that would require additional review by USDA.

Basis for GRAS determination

Scientific procedures are the basis for this GRAS determination. An independent and critical evaluation of the safety and GRAS status of the intended use of *Bacillus coagulans* GBI-30, 6086 was conducted by an expert panel qualified by training and/or experience to evaluate the safety of food ingredients. The expert panel consisted of Theodore Farber, PhD, Judith Hauswirth, PhD, Alexander Schauss, PhD, FACN and John Endres, ND. The panel critically evaluated the scientific research available with regard to *Bacillus coagulans* GBI-30, 6086 and collectively determined that the ingredient is GRAS for its intended use in food. The expert panel believes that other qualified scientists reviewing the same publically available data would come to the same conclusion.

Data and Information Availability Statement

The data and the information that serve as the basis for this GRAS determination will be available for review and copying at reasonable times at the office of David Keller, DPM, MBA, Vice President of Scientific Operations, Ganeden Biotech, Inc., 5915 Landerbrook Drive, Suite 304, Mayfield Heights, Ohio 44124 Telephone: (440) 229-5200 email: keller@ganedenbiotech.com or will be sent to the FDA upon request.

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Characterization

Bacillus coagulans was first described in 1915 at the Iowa Agricultural Experiment Station, with regard to the coagulation of canned evaporated milk.[1] GanedenBC^{30} is the trade name for a proprietary preparation of a *Bacillus coagulans* strain designated as *Bacillus coagulans* GBI-30, 6086. *Bacillus coagulans* GBI-30, 6086 is a patented probiotic organism. It is L+ lactic acid producing, non-toxicogenic, and non-pathogenic. The organism is a gram-positive spore-forming rod that is aerobic to microaerophilic in nature. Its size is 0.9 μm x3.0 μm x5.0 μm. *Bacillus coagulans* GBI-30, 6086 is manufactured as a pure cell mass consisting solely of *Bacillus coagulans*. The pure cell mass is freeze-dried or spray-dried and blended with maltodextrin, microcrystalline cellulose, or sodium bicarbonate to achieve the desired concentration of the finished product. For the purpose of the toxicological studies described below, pure *Bacillus coagulans* GBI-30, 6086 was used. The concentration varies slightly from batch to batch and therefore is reported for each study.

DNA Ribotyping Analysis

16S Ribosomal DNA base pair analysis of *Bacillus coagulans* GBI-30, 6086 was performed and *Bacillus coagulans* GBI-30, 6086 was identified to the genus level with a 99% confidence level. The resulting base pair data and the base pair analysis for a known strain of *Bacillus coagulans* (Hammer strain), from which the *Bacillus coagulans* GBI-30, 6086 originates, and that is deposited at the NBRC (National Institute of Technology and Evaluation Biological Resource Center: 2-49-10 Nishihara, Shibuya-ku, Tokyo, 151-0066 Japan) as (NBRC3887 a.k.a IFO 3887 Nakayama) was compared using GenBank®, the NIH genetic sequence database. *Bacillus coagulans* GBI-30, 6086 differed in only 2 of 514 base pairs. Thus, it was verified that *Bacillus coagulans* GBI-30, 6086 is indeed a pure strain of *Bacillus coagulans* Hammer. Midi Labs (Newark, DE) tested a batch of *Bacillus coagulans* GBI-30, 6086 and also found a 99% match with Genbank and a difference of only 2-1/2 base pairs between three lots of *Bacillus coagulans* GBI-30, 6086.

As a part of Ganeden's ongoing QC program, each and every lot of *Bacillus coagulans* GBI-30, 6086 is analyzed by 16S Ribosomal DNA base pair analysis at Ganeden's state of the art laboratory.

Other Ingredients

The other ingredients in the final product, *Bacillus coagulans* GBI-30, 6086, consist of maltodextrin, microcrystalline cellulose and/or sodium bicarbonate, which are used for bulking purposes. These bulking agents are all GRAS as per: 21 CFR 184.1444 (maltodextrin) and 184.1736 (sodium bicarbonate). The GRAS status of microcrystalline cellulose is included in the Select Committee on GRAS Substances (SCOGS) review of ethyl cellulose. All corn-derived products used in the production of *Bacillus coagulans* GBI-30, 6086 are manufactured to meet

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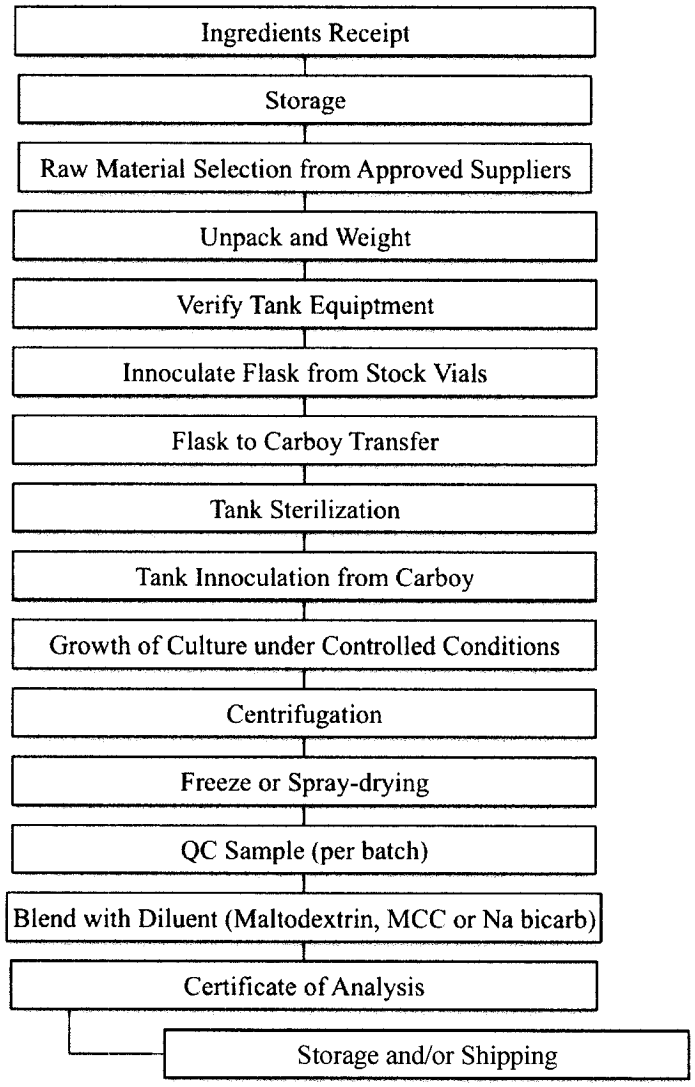
European Union quality standards (EC 1829, EC 1830), which does not allow for GMO products.

Manufacturing and Production

The production process for *Bacillus coagulans* GBI-30, 6086 consists of fermentation followed by recovery, followed by spray-drying or freeze-drying. The purpose of the recovery process (centrifugation) is to retrieve and concentrate *Bacillus coagulans* post-fermentation.

Figure 1. Manufacturing Flow Chart



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Product Specifications and Non-sequential Lot Analysis

The summary of the certificates of analysis below includes physical specifications, bacteriological count, heavy metal testing, and microbial testing.

Table 1. Product specifications and lot analyses

	Product Specifications	Method	Lot Number				
Physical Specifications			23-Dec-08	15-Apr-09	23-Jul-09	20-Oct-09	22-Oct-09
CFUs/g	NLT 15 x 10^9	Ganeden QC0229	20.4 X 10^9	21.8 X 10^9	22.6 X 10^9	23.0 X 10^9	20.0 X 10^9
Appearance	White to beige powder	Visual	√	√	√	√	√
Moisture	NMT 10%	AOAC 926.08	2.7	5.1	5.6	5.3	5.2
Sieve Test	100% through 40 mesh	Internal Method	√	√	√	√	√
Sieve Test	98% through 80 mesh	Internal Method	√	√	√	√	√
Heavy Metals Analysis							
Arsenic	NMT 2 ppm	AOAC 984.27	<0.98	<1.0	<0.99	<0.99	<0.98
Cadmium	NMT 2 ppm	AOAC 984.27	<0.20	<0.20	<0.20	<0.20	<0.20
Lead	NMT 5 ppm	AOAC 984.27	<0.49	<0.50	<0.50	<0.49	<0.49
Mercury	NMT 2 ppm	EPA 7471	<0.05	<0.05	<0.05	<0.05	<0.05
Microbiological Analysis							
Yeast	Report CFUs/g	BAM CH. 18	none detected	none detected	<10	<10	<10
Total Coliforms	NMT 3 MPN/g	BAM CH. 4	<3	<3	<3	<3	<3
E. coli	Absent	BAM CH. 4	none detected	none detected	none detected	none detected	none detected
Staphylococci	Absent/25g	AOAC 975.55	none detected	none detected	none detected	none detected	none detected
Salmonella	Absent/25g	AOAC 992.11	none detected	none detected	none detected	none detected	none detected
P. aeruginosa	Absent	Internal Method	none detected	none detected	none detected	none detected	none detected

Shelf-life Stability

An accelerated shelf-life stability study was performed to assess the stability of *Bacillus coagulans* GBI-30, 6086, lot number [redacted] after three months, having been stored at 40°C and 75% relative humidity (see **Table 2**). A real time shelf-life stability study has been placed and will continue for 36 months.

Table 2. Shelf-life Stability

***Bacillus coagulans* enumeration**	**Time Period of Analysis**	
	Initial	**3 months**
	1.8 x 10^{10} cfu/g	1.8 x 10^{10} cfu/g

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Self-limiting Levels of Use

There are no inherent self-limiting levels of use.

Safety Assessment

Toxicology Studies

Bacterial reverse mutation study of *Bacillus coagulans* GBI-30, 6086 cell mass

The bacterial reverse mutation assay was performed to evaluate whether *Bacillus coagulans* GBI-30, 6086 cell mass has mutagenic properties. The study was conducted according to Organization for Economic Cooperation and Development (OECD) Guidelines for the Testing of Chemicals: Bacterial Reverse Mutation Test (Guideline 471, as adopted July 21, 1997). The plate incorporation method was employed for this study with five doses in triplicate on four *Salmonella typhimurium* (TA98, TA100, TA1535, TA1537) and one *E. coli* (WP2 [uvrA]) tester strains with and without an S9 activation system. Doses used in the definitive study were: 10, 50, 100, 500, and 5,000 μg per plate. The plates were read after 72 hours of incubation. Distilled water was used as a vehicle control and the appropriate positive control was used for each of the tester strains with and without S9 metabolic activation.

There were no revertants exceeding three times the background average either with or without the S9 metabolic activation system. In addition, no dose-dependent increase in revertants was observed. In conclusion, the results of this study showed that the *Bacillus coagulans* cell mass (*Bacillus coagulans* GBI-30, 6086) had no mutagenic effect on any strain used in this test. Furthermore, the results of the repeat assay confirmed the results of the definitive assay.[2]

Mouse Micronucleus Study

The micronucleus test was conducted to investigate for the formation of micronuclei containing chromosomal fragments or whole chromosomes, which are indicative of cytogenetic damage. Male mice of strain BALB/dByJNarl, aged 7–8 weeks were assigned randomly to five groups of five, and were housed five animals per cage. The test article was obtained at a concentration of 1.93×10^{11} CFUs/g. Mitomycin C served as the positive control. Doses of test article included 500, 1000 and 2000 mg/kg bw/day given orally for three days.

There were no differences in body weight between the treatment groups compared to the control group and no signs of toxicity were noted in clinical observations following administration of the test article at doses of 500, 1000 and 2000 mg/kg bw/day. Animals in the positive control group showed a significant increase in the frequency of micronuclei compared to the negative controls. None of the treatment groups were positive for statistically significant induction of micronuclei in reticulocytes, and the ratio of reticulocytes to total erythrocytes in

these groups showed no significant decrease compared to the negative control group. The average reticulocyte to total erythrocytes ratio in the negative control group was 3.87%. The treatment groups were 3.69%, 3.65% and 3.69% in the 500, 1000 and 2000 mg/kg bw/day groups respectively. The positive control caused a 32.8% decrease in the ratio.

The incidence of micronucleated reticulocytes in the peripheral blood per 1000 reticulocytes was 1.8 ±0.8 in the negative control group, which was within the historical reference range. The positive control group had a mean frequency of 31.2 ±5.5, which was a statistically significant increase compared with the negative control group. The test article dose groups had 1.3 ±1.2, 2.2 ±1.0 and 0.9 ±0.4 micronucleated reticulocytes per 1000 reticulocytes, at the test dose levels of 500, 1000, and 2000 mg/kg bw/d respectively. These values were not statistically significant, and thus did not demonstrate any signs of toxicity with administration of *Bacillus coagulans* GBI-30, 6086 in the mouse peripheral blood micronucleus assay.[2]

Chromosomal Aberration Study

The purpose of performing the chromosomal aberration assay in cultured mammalian cells is to investigate for any potential the test article may have for causing structural damage to either chromosomes or chromatids. Chinese hamster ovary cells (CHO-K1), and test article concentrations of 312.5, 625, 1250, 2500 and 5000 μg/mL were utilized in the study. The test article was originally obtained at a concentration of 1.93 10^{11} CFUs/g. Three treatment schemes were utilized, including incubation of the test article with cells for 3 h both with and without an S9 metabolic activation system (Schemes I and II, respectively), and incubation for 20 h without S9 (Scheme III).

Cells in the negative control group had 20 ±2 chromosomes upon karyotypic analysis. The percentage of chromosomal aberrations measured in the negative control groups was zero. None of the dose levels of *Bacillus coagulans* GBI-30, 6086 tested produced any statistically significant increase in aberrant cells, while the positive control groups (one micromolar mitomycin C) did induce a significant increase when compared with the negative controls as expected. Therefore, under the conditions of the assay, *Bacillus coagulans* GBI-30, 6086 produced a negative response for induction of structural chromosomal aberrations both with and without the metabolic activation system in Chinese hamster ovary cells.[2]

Acute Oral Toxicity Study

An acute oral toxicity study of a *Bacillus coagulans* cell mass with a 14-day post-treatment observation period in rats (limit test) was performed using *Bacillus coagulans* GBI-30, 6086 cell mass from lot number [redacted], which had a concentration of 1.04 X 10^{11} CFUs/g per the certificate of analysis. A single oral dose of 5,000 mg/kg body weight of *Bacillus coagulans* GBI-30, 6086 was administered by gavage to the treatment group consisting of five male and five

female CRL:(WI) BR Wistar rats. Methylcellulose solution of 1% was administered to the control group (same number of animals) by oral gavage. The animals were weighed, observed for clinical signs, and checked for lethality for each of 14 days. A gross and histopathological examination was performed on day 15. The study was performed using guidelines from FDA Redbook II Draft Guidance, Acute Oral Toxicity Tests (1993) and OECD Guidelines for the Testing of Chemicals No. 423 (adopted December 17, 2001).

No mortality, adverse clinical signs, or weight-loss was observed. All animals survived until the time of the necropsy. All of the organs of the male and female rats were free from gross pathological changes related to the single oral administration of 5,000 mg/kg *Bacillus coagulans* GBI-30, 6086.

It should be noted that when manufacturing the final product, *Bacillus coagulans* GBI-30, 6086 is mixed with a diluent to a establish a consistent concentration of 15 X 10^9 CFUs/g. However, for the purpose of this study, uncut *Bacillus coagulans* GBI-30, 6086 cell mass was used. The concentration of this uncut test article (lot # [redacted] was 1.04 X 10^{11} CFUs/g (hence 5.2 X 10^{11} CFUs/kg in this study), which is 6.933 times greater concentration than *Bacillus coagulans* GBI-30, 6086—the finished product. So, while the LD-50 is greater than 5,000 mg/kg in this study, for the undiluted *Bacillus coagulans* cell mass, it is equivalent to 34,655 mg/kg of *Bacillus coagulans* GBI-30, 6086, the product under consideration for this GRAS self-affirmation.[2]

Subchronic 13-Week Oral Toxicity Study in Rats

The objective of this study was to evaluate for repeated oral toxicity of *Bacillus coagulans* GBI-30, 6086 cell mass in rats over a 13-week period, and to characterize the potential adverse effects of the substance and indicate target organs. The study was performed using guidelines from FDA Redbook II Draft Guidance, Short-term Toxicity Studies with Rodents (2003) and OECD Guidelines for the Testing of Chemicals No. 403 (adopted September 21, 1998). The test article was administered orally by gavage to CRL:(WI) BR Wistar rats for 90 consecutive days. Dose levels administered were as follows: 0 mg/kg body weight per day (vehicle control), 100, 300, and 1000 mg/kg body weight per day in both male and female animals. The test item was suspended in 1% aqueous methylcellulose solution. The treatment volume was 10 mL/kg body weight in each group.

General clinical observations were made once daily. Detailed clinical observations were made prior to the first exposure and once per week thereafter. Behavioral (spontaneous activity, motor affective responses, sensori-motor responses), neurological (posture, muscle tone, equilibrium and gait, central nervous system excitation) and autonomic (eye, secretion, excretion) functions were observed. Functional Observation Battery was performed on the 13th week of the treatment. Body weight and food consumption were measured weekly. Blood sampling for clinical pathology and gross pathology were conducted at the end of the treatment period. Selected organs were weighed. Gross and

histopathological examinations were performed on fixed organs and tissues from the control and highest dose group (and middle dose groups as appropriate).

No mortalities were observed throughout the study. The daily general observations and the weekly detailed observations did not result in test-item related clinical signs. In evaluation of the Functional Observation Battery results, only one individual variation was found without a trend.

The mean body weight of the males in the 100 mg/kg group was below that of the controls on day 50, and from days 71 to 90 in the study. The difference was 6–7% lower than the control groups, but was not considered related to the test article because of a lack of a dose response. The mean body weight of the males in the 1000 mg/kg group was lower than the control groups, in this case, from days 22–90. No statistically significant differences in body weight were noted in the male or female rats in the 300 mg/kg group, when compared to the control. Similar effects were not observed in the female rats in any of the treatment groups.

Average daily food consumption was similar in all groups except for a slightly lower mean value ($p<0.05$) with the males in the highest dose group during week 8, and a slightly higher mean value ($p<0.01$) with the females in the highest dose group during week 6. Water consumption for all of the male dose groups was similar when compared with the controls. Statistically significant lower water consumption ($p<0.05$) was noted in the females in the 100 mg/kg group during days 57–58 and 88–89, and in the females in the 300 mg/kg group ($p<0.05$) on days 57–58, 85–86 and 88–89. Females in the 1000 mg/kg dose group also had decreased water consumption, but only during days 57–58 ($p<0.01$) and 88–89 ($p<0.05$).

Some statistically significant differences were observed from the results of the hematology and clinical chemistry parameters tested. However, since they fell into the historically normal range for the laboratory, it was concluded that no clinically relevant test item related hematological or clinical chemistry changes were observed in either the male or female rats receiving *Bacillus coagulans* GBI-30, 6086 at 100, 300, or 1000 mg/kg/day.

Gross pathological evaluation at the end of the study revealed several cases of pinprick-sized hemorrhages and pale, pillow-like raised areas in the lungs in all groups, which were likely caused by exsanguination of the animals. No treatment-related histopathological findings were noted upon examination of the animals at the end of the study.

Absolute organ weights differed only in the brains of the males in the 1000 mg/kg group (lower), the liver in the 100 and 1000 mg/kg groups (lower), and the testes in the 100 mg/kg group (lower). However, the differences were considered to be the consequence of the lower mean body weights of these groups. Importantly, the relative organ weights compared to body weights did not differ for these organs.

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The relative kidney weight was lower than the control in the males in the 300 mg/kg group, and higher in the males in the 1000 mg/kg group. The changes were not considered to be of biological significance or related to the test article, most importantly because they were not corroborated with any histological findings. The relative weight of the adrenal glands was lower than the control group for the females in the 300 mg/kg group, but was due to individual variation and not considered related to administration of the test article because of a lack of a dose response.

In the 90-day subchronic oral toxicity study, no toxicologically significant differences between the treated groups (100, 300 and 1000 mg/kg bw/day) and the controls were observed with respect to food consumption, water consumption, sensory reactivity, general and behavioral conditions, hematological and clinical chemistry evaluations. *Bacillus coagulans* GBI-30, 6086 caused neither treatment-related macroscopic or microscopic signs nor changes in the organ weights of the male and female rats at 100, 300 and 1000 mg/kg/day after the 13-week treatment period. The test article was well tolerated.

Since there were no signs of toxicity noted with respect to gross or histopathological examinations, nor with hematology, clinical chemistry, or organ weights for the 1000 mg/kg dose group, the differences in the mean body weight of the males described above is not considered related to the test article, but rather a result of biological variation. Hence, the NOAEL for both males and females is considered to be 1000 mg/kg body weight per day, which was the highest dose tested.

As described above, it should be noted that in manufacturing of the final product, *Bacillus coagulans* GBI-30, 6086 is diluted with maltodextrin, microcrystalline cellulose and/or sodium bicarbonate to a concentration of 15 X 10^9 CFUs/g. For the purpose of this study, undiluted *Bacillus coagulans* cell mass was used. The concentration of this undiluted test article (lot [redacted] was 1.36 X 10^{11} CFUs/g, which is 9.07 times greater concentration than *Bacillus coagulans* GBI-30, 6086. So, the NOAEL of 1,000 mg/kg for the undiluted *Bacillus coagulans* cell mass used in this study, is equivalent to 9,070 mg/kg of *Bacillus coagulans* GBI-30, 6086.[2]

As referenced, the results of the toxicological studies performed prior to the completion of the 1-year study were published in 2009. Please note the citation below:

Endres JR, Clewell A, Jade KA, Farber T, Hauswirth J, Schauss AG. Safety assessment of a proprietary preparation of a novel probiotic, *Bacillus coagulans*, as a food ingredient. *Food and Chemical Toxicology*. 2009;47(6):1231–1238.

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1-Year Chronic Oral Toxicity Study in Rats with 1-Generation Reproduction Toxicity

Introduction

The objective of this study was to evaluate the potential toxicity of chronic oral consumption of *Bacillus coagulans* cell mass as *Bacillus coagulans* GBI-30, 6086, and to assess for any reproductive toxicity, as well as to confirm the findings of the 90-day repeated oral toxicity study in the rat described above. The study was designed and conducted according to the guidelines suggested by the Toxicological Principles for the Safety Assessment of Food Ingredients (USFDA Office of Food Additive Safety Redbook 2000) IV.C.5a. Chronic Toxicity Studies with Rodents (July, 2007) and IV.C.9a Guidelines for Reproduction Studies (July, 2000) and OECD Guidelines for the Testing of Chemicals, No. 452 (adopted May 12, 1981).

Table 3. Test article dose levels for the main group (20 animals/sex/group)

Group	Test article concentration in diet (ppm)		Target dose level	Actual dose level (mg/kg bw/day)	
	Nominal	Real	mg/kg bw/day	Male	Female
1	0	0	0	0	0
2	10 000	10 000	600	585	761
3	20 000	20 000	1200	1146	1467
4	33 300	33 300	2000	1948	2526

Table 4. Test article dose levels in the satellite group (10 males and 20 females per group)

Group	Test article concentration in diet (ppm)		Target dose level	Actual dose level (mg/kg bw/day)	
	Nominal	Real	mg/kg bw/day	Male	Female
1	0	0	0	0	0
2	10 000	10 000	600	715	1079
3	20 000	20 000	1200	1348	2082
4	33 300	33 300	2000	2372	3558

The concentration, homogeneity, and viability of the test article were analyzed for each of the doses for each batch of feed produced throughout the study. Each lot of feed produced was found to be viable, met or exceeded the target dose level, and were homogeneous throughout the lots produced.

Hsd.Brl.Han Wistar rats between 7–9 weeks of age were used for the study. The animals were housed individually in type II polypropylene/polycarbonate cages. The rats were acclimatized for 14 days prior to the start of the study. Only healthy animals, free from any clinical signs were used.

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For the main study, 20 animals per sex per group were randomized. For the reproduction study, satellite groups consisting 10 males and 20 females were randomized. For mating, a ratio of one male to one female was used with a three hour per day mating time each morning for three weeks. The presence of a vaginal plug or sperm indicated the day of mating, which was considered day 0 of the pregnancy.

General clinical observations were made once daily at roughly the same time each day. Detailed clinical observations for the main group were made prior to the start of the study and then once weekly in an arena outside of the home cage through to the end of the study. Observations included: skin, fur, eyes, mucous membranes, lachrymation, piloerection, pupil size, respiration, circulation, central nervous system, somato-motor system activity, behavior, gait, posture, response to handling, as well as particular attention for the observation of any tremors, convulsions, excessive salivation, diarrhea, lethargy, sleep, and coma.

All animals were weighed at the time of randomization and day 0 of the study. Body mass was recorded weekly for the first 13 weeks and then monthly for the duration of the study.

In the satellite groups, male rats were weighed weekly until necropsy. The females in the same group were weighed weekly through mating and then on gestation days: 0, 7, 14, 21 as well as on lactation days: 0, 7, 14, and 21. Live pups were counted and weighed on the morning after birth and on days 4 and 7, and then weekly thereafter until termination of the study.

Food was weighed weekly and the daily average food consumption per rat was calculated.

In the reproduction study, the females were allowed to litter and rear their offspring. The development of the pups was assessed by the surface righting reflex, pinna detachment and eye opening.

Clinical testing consisted of: ophthalmoscopy, pathology, hematology, coagulation studies, clinical chemistry, and urinalysis.

Pathological examination began with necropsies on week 53. The animals were observed for external appearance of the cranial, thoracic, and abdominal cavities. The adrenal glands, aorta, femur bone marrow, brain, eyes, mammary gland (females), gonads (both sexes), gross lesions, heart, kidneys, large intestine, small intestine, liver, lungs, lymph nodes (submandibular and mesenteric), quadriceps muscle, esophagus, pancreas, pituitary gland, prostate, submandibular salivary gland, sciatic nerve, seminal vesicle, skin, spinal cord (cervical, mid-thoracic, lumbar), spleen, sternum, stomach, thymus gland, thyroid gland, parathyroid gland, trachea, and the urinary bladder were preserved for histopathological examination.

The liver, brain, heart, thymus, spleen, kidneys, testes, epididymides, uterus, thyroid, parathyroid, adrenal glands, and ovaries were weighed. Paired organs were weighed together.

Complete histopathological examination was performed in the control and the highest dose group tested in the main study (groups 1 and 4 respectively). The following organs of all male and females parent animals in the satellite group were examined histopathologically: ovaries, uterus, cervix, vagina, testes, epididymides, seminal vesicles, prostate, coagulating gland, and pituitary gland.

Main Study

There was no test article related mortality. One female animal of 1,200 mg/kg bw/day was found dead on day 137 as a consequence of an individual disorder, which was concluded on the basis of clinical observations. Gross pathology and histopathological evaluation was not possible because autolysis of the organ systems had occurred prior to discovering the dead animal. Two female animals (one in the control group and one in the 2,000 mg/kg bw/day group) were euthanized during the treatment period because of their moribund condition. Gross pathological and histopathological examinations revealed individual disease in both animals such as diffuse subacute dermatitis resulting in cachexia, and generalized fibrosarcoma, respectively. This was not considered due to the test article.

General daily and detailed clinical observations did not reveal any toxic signs related to the test article. Any clinical signs observed occurred mainly in female animals (irritability, decreased body tone and grip tone, as decreased righting reflex, alopecia and scars on the skin, sanguineous eye with swelling) were with low incidence. These observations are seen occasionally in experimental rats and were not related to the doses in this study.

No test article-related body weight, or body weight gain changes were observed during the study. The mean daily food consumption was similar in the control and test article treated groups.

There were no eye alterations observed in any of the groups in the study. Laboratory examinations did not reveal any test article related pathological changes in the evaluated hematological, clinical chemistry or urine parameters at the end of the 3rd week, as well as the 3rd, 6th or 12th months. Changes observable in all groups of treated male and female rats were not toxicologically relevant as alterations noted were either not related to administered dose, lying well within the historical background range or were not correlated with other hematological or histopathological alterations.

Macroscopic alterations observed during terminal necropsy were comparable in both the treatment groups and the control animals, and could not be attributed to administration of the test article.

There were no test article related changes in the examined organ weights. Histopathological evaluation of the organs of the experimental animals did not reveal lesions attributable to the effect of test article.

In conclusion, *Bacillus coagulans* GBI-30, 6086 caused no signs of toxicity in male or female Hsd.Brl.Han: Wistar rats after one year of diet-mixed administration.

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Based on the observations made in this dietary toxicity study, the dietary No Observed Effect Level (NOEL) was determined to be 33,300 ppm for male and female Hsd.Brl.Han: Wistar which corresponds to a mean daily intake of:

- NOEL for male rats: 1948 mg/kg bw/day (mean value)
- NOEL for female rats: 2525 mg/kg bw/day (mean value)

Reproduction study

No animals of parental generation died during the observation period. There were no test article related effects on the general state and behavior of parental animals during the pre-mating, mating, gestation and lactation periods.

The body weight, body weight gain of male and female parental animals was unaffected at the examined dose levels during the pre-mating period. There was no effect on body weight, body weight gain of the dams during the gestation and lactation period at the examined dose levels.

No differences were seen in food consumption in males of all three treatment groups during the pre-mating and post-mating periods, or in females of all treatment groups during the pre-mating, gestation and lactation periods, when compared to controls.

There was no test article influence on the estrous cycle, mating, fertility, gestation period, or for the delivery of dams when compared with the control animals. Reproductive performance of males and females were unaffected by treatment with test article.

Macroscopic observations of organs and tissues did not reveal alterations due to the effect of the test article in P generation. No test article related organ weight changes were found in parental male or female animals.

No histopathological alterations related to the test article effect were found. In the male animals, the investigated organs of the reproductive system (testes, epididymides, seminal vesicles, prostate, coagulating gland) were histologically normal. In dams, the ovaries had a normal structure characteristic of the species, age and phase of the active sexual cycle. The uterus, cervix, and vagina had a normal structure in accordance with the phase of sexual cycle in the investigated animals.

No test article related alterations were found in the F1 generation. The mortality, viability, sex ratio, body weight and body weight gain, postnatal development of the pups was similar in the control and the test article treated groups.

In conclusion, *Bacillus coagulans* GBI-30, 6086 caused no signs of toxicity in the parental generation (male or female) of Hsd.Brl.Han:Wistar rats during the course of this one reproductive toxicity study. Reproductive performance of males and females were unaffected by the treatment and there was no effect on mortality or postnatal development of pups.

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Based on the observations, the dietary No Observed Effect Level (NOEL) for the reproductive study was determined to be 33,300 ppm for male and female Hsd.Brl.Han:Wistar, which corresponds to a mean daily intake of the following:

- NOEL for parental male rats: 2372 mg/kg bw/day (mean value)
- NOEL for parental female rats: 3558 mg/kg bw/day (mean value)
- NOEL for reproductive performance of male rats: 2372 mg/kg bw/day (mean value)
- NOEL for reproductive performance of female rats: 3558 mg/kg bw/day (mean value)
- NOEL for F1 Offspring: 3558 mg/kg bw/day (mean value)

The results of this toxicological study were published in 2011. Please note the citation below:

Endres JR, Qureshi I, Farber T, Hauswirth J, Hirka G, Pasics I, Schauss AG. One-year chronic oral toxicity with combined reproduction toxicity study of a novel probiotic, *Bacillus coagulans*, as a food ingredient. *Food and Chemical Toxicology*. 2011;49(5):1174–1182.[3]

Acute Eye Irritation Study in Rabbits

An acute eye irritation study was performed in New Zealand White rabbits using undiluted *Bacillus coagulans* GBI-30, 6086 cell mass from lot number [redacted] which had a concentration of 1.93 X 10^{11} CFUs/g per the certificate of analysis. The study concluded that *Bacillus coagulans* GBI-30, 6086 applied to the mucosa of the rabbit's eyes resulted in a slight to moderate conjunctival irritant effect that was fully reversible within 72 hours. According to EC criteria for classification and labeling requirements for dangerous substances and preparations, obligatory labeling of the test article is not required with regard to eye irritation.[2]

Acute Skin Irritation Study

An acute skin irritation study was performed in New Zealand White rabbits using the undiluted *Bacillus coagulans* cell mass (*Bacillus coagulans* GBI-30, 6086) from lot number [redacted], which had a concentration of 1.93 X 10^{11} CFUs/g per the certificate of analysis. The irritation effect of the test article was evaluated according to the Draize method (OECD 404, 2002). According to EEC directive 2001/59/EEC the test article is not classified as irritating to the skin. The observed clinical sign of very slight erythema on the treated skin surface was evaluated as fully reversible.[2]

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General Recognition

The scientific studies mentioned above that provide the pivotal basis of this GRAS determination by scientific procedures, are published and available in the public domain. The general availability of this information satisfies the common knowledge component of this GRAS notification. The results of the toxicological studies were published in 2009 and 2011 in the peer reviewed journal *Food and Chemical Toxicology*, and the full-text articles have been made available for free from the journal website, to allow maximal accessibility of the information. The publications include the follow studies: the *in vitro* bacterial reverse mutation assay, the *in vitro* chromosomal aberration assay, the micronucleus assay in the mouse, the acute eye and skin irritation studies in the rabbit, and the acute, subchronic and chronic oral toxicity studies (including the combined reproduction toxicity study) in the rat. Please note the citations for the publications below:

Endres JR, Clewell A, Jade KA, Farber T, Hauswirth J, Schauss AG. Safety assessment of a proprietary preparation of a novel probiotic, *Bacillus coagulans*, as a food ingredient. *Food and Chemical Toxicology*. 2009;47(6):1231–1238.

Endres JR, Qureshi I, Farber T, Hauswirth J, Hirka G, Pasics I, Schauss AG. One-year chronic oral toxicity with combined reproduction toxicity study of a novel probiotic, *Bacillus coagulans*, as a food ingredient. *Food and Chemical Toxicology*. 2011;49(5):1174–1182.

Additional Support of Safety

The section below is included as a history of human exposure and other scientific and evidence-based research that corroborates the safety of consumption of *Bacillus coagulans* GBI-30, 6086 demonstrated by the safety studies based upon scientific procedures.

1. In a statement regarding the US FDA GRAS of an insoluble glucose isomerase enzyme preparation derived from *B. coagulans* the Agency states: "Insoluble glucose isomerase enzyme preparations are derived from recognized species of precisely classified, **nonpathogenic**, and **nontoxicogenic** microorganisms, including *Streptomyces rubiginosus, Actinoplane missouriensis, Streptomyces olivaceus, Streptomyces olivochromogenes* and ***Bacillus coagulans*** grown in a pure culture fermentation that produces no antibiotic." (21 CFR 184.1372)
2. ATCC classifies *B. coagulans* as BSL-1, which means it is not known to cause disease in healthy adult humans.

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3. Health Canada lists *B. coagulans* as a non-pathogenic, non-toxicogenic organism. Thus they state that no import permit is required.
4. There are no adverse events reported on the FDA Safety Information and Adverse Event Reporting Program (Medwatch) from consumption of *Bacillus coagulans* GBI-30, 6086 as per this writing.
5. Six human studies using *Bacillus coagulans* GBI-30, 6086 have been published in peer-reviewed academic journals between 2009 and 2010.[4-9] While the studies were designed to detect efficacy as a medical food or dietary supplement, rather than safety, the six publications are included in this safety assessment because they demonstrate a lack of adverse events when *Bacillus coagulans* GBI-30, 6086 is administered to human study subjects. The studies can be found in the attached documents.
6. Dr. Brad Goodner, PhD, Edward J. Smerek Endowed Chair in Mathematics, the Sciences, & Technology and Professor of Biology at Hiram College conducted a study to investigate *Bacillus coagulans* GBI-30, 6086 for any evidence of genes encoding for enterotoxin and haemolysin using PCR primer technology (unpublished data). Primers were employed that were previously described by Hansen, et al. 2001 in an article entitled: Detection of enterotoxic *Bacillus cereus and Bacillus thuringiensis* strains by PCR analysis. The investigation by Dr. Goodner resulted in a clear conclusion that "there is no evidence that *Bacillus coagulans* in general and the BC30 strain in particular produces any sort of enterotoxin or haemolysin."
7. The European Food Safety Authority (EFSA), in The EFSA Journal (2007) 587, 8-16, proposed that *Bacillus coagulans* receive a qualified presumption of safety (QPS). The qualifications include: (1) Absence of emetic food poisoning toxins with surfactant activity, and (2) Absence of enterotoxic activity. To the best of our knowledge, there is nothing in the literature to suggest that *B. coagulans* or *Bacillus coagulans* GBI-30, 6086 exhibits either of these characteristics (#1 and #2 above). Furthermore, this is corroborated by the enterotoxin and haemolysin study described above as well as the absence of adverse events in the human studies conducted with *Bacillus coagulans* GBI-30, 6086.

Intended Use

Bacillus coagulans GBI-30, 6086 is intended for use in a wide variety of food. The food categories as defined in 21CFR 170.3(n) to which *Bacillus coagulans* GBI-30, 6086 will be added are listed in **Table 5** below.

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Table 5. Intended Food Categories as per 21CFR170.3(n)

(1) Baked goods and baking mixes, including all ready-to-eat and ready-to-bake products, flours, and mixes requiring preparation before serving.
(2) Beverages, alcoholic, including malt beverages, wines, distilled liquors, and cocktail mix.
(3) Beverages and beverage bases, nonalcoholic, including only special or spiced teas, soft drinks, coffee substitutes, and fruit and vegetable flavored gelatin drinks.
(4) Breakfast cereals, including ready-to-eat and instant and regular hot cereals.
(5) Cheeses, including curd and whey cheeses, cream, natural, grating, processed, spread, dip, and miscellaneous cheeses.
(6) Chewing gum, including all forms.
(7) Coffee and tea, including regular, decaffeinated, and instant types.
(8) Condiments and relishes, including plain seasoning sauces and spreads, olives, pickles, and relishes, but not spices or herbs.
(9) Confections and frostings, including candy and flavored frostings, marshmallows, baking chocolate, and brown, lump, rock, maple, powdered, and raw sugars.
(10) Dairy product analogs, including nondairy milk, frozen or liquid creamers, coffee whiteners, toppings, and other nondairy products.
(12) Fats and oils, including margarine, dressings for salads, butter, salad oils, shortenings and cooking oils.
(16) Fresh fruit juices, including only raw fruits, citrus, melons, and berries, and home-prepared "ades" and punches made therefrom.
(20) Frozen dairy desserts and mixes, including ice cream, ice milks, sherbets, and other frozen dairy desserts and specialties.
(21) Fruit and water ices, including all frozen fruit and water ices.
(22) Gelatins, puddings, and fillings, including flavored gelatin desserts, puddings, custards, parfaits, pie fillings, and gelatin base salads.
(23) Grain products and pastas, including macaroni and noodle products, rice dishes, and frozen multicourse meals, without meat or vegetables.
(25) Hard candy and cough drops, including all hard type candies.
(26) Herbs, seeds, spices, seasonings, blends, extracts, and flavorings, including all natural and artificial spices, blends, and flavors.
(28) Jams and jellies, commercial, including only commercially processed jams, jellies, fruit butters, preserves, and sweet spreads.
(30) Milk, whole and skim, including only whole, lowfat, and skim fluid milks.
(31) Milk products, including flavored milks and milk drinks, dry milks, toppings, snack dips, spreads, weight control milk beverages, and other milk origin products.

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(32) Nuts and nut products, including whole or shelled tree nuts, peanuts, coconut, and nut and peanut spreads.

(33) Plant protein products, including the National Academy of Sciences/National Research Council "reconstituted vegetable protein" category, and meat, poultry, and fish substitutes, analogs, and extender products made from plant proteins.

(35) Processed fruits and fruit juices, including all commercially processed fruits, citrus, berries, and mixtures; salads, juices and juice punches, concentrates, dilutions, "ades", and drink substitutes made therefrom.

(36) Processed vegetables and vegetable juices, including all commercially processed vegetables, vegetable dishes, frozen multicourse vegetable meals, and vegetable juices and blends.

(37) Snack foods, including chips, pretzels, and other novelty snacks.

(38) Soft candy, including candy bars, chocolates, fudge, mints, and other chewy or nougat candies.

(40) Soups and soup mixes, including commercially prepared meat, fish, poultry, vegetable, and combination soups and soup mixes*.

(41) Sugar, white, granulated, including only white granulated sugar.

(42) Sugar substitutes, including granulated, liquid, and tablet sugar substitutes.

(43) Sweet sauces, toppings, and syrups, including chocolate, berry, fruit, corn syrup, and maple sweet sauces and toppings.

**Bacillus coagulans* GBI-30, 6086 is not intended for use in any product that would require additional review by USDA.

Bacillus coagulans GBI-30, 6086 is currently added to foods at a level of 100 X 10^6 to 2 x 10^9 CFUs per serving. The acceptable daily intake (ADI) concluded from the GRAS self-declaration is 93.8 x 10^9 CFUs (the derivation of this number can be found in the 2011 publication of the one-year repeated dose toxicological study by Endres and colleagues). At the current and intended addition level per serving to foods, between 46.9 and 938 servings of food per day would have to be consumed to exceed the *Bacillus coagulans* GBI-30, 6086 ADI.

According to the *USDA Nutrition Insights*, a publication of the USDA Center for Nutrition Policy and Promotion, October 2000,[10] males aged 51 or older consume the greatest servings of food per day. They consume 18.2 servings of food per day from the following categories: grains, fruits, vegetables, milk, meat and other (fats, oils, sweets). Therefore, even if *Bacillus coagulans* GBI-30, 6086 were added to every category of food outlined above, at current and intended addition levels, the ADI would not be exceeded. Therefore, based upon the greatest estimate of servings of food consumed per day in the US and the higher addition level of *Bacillus coagulans* GBI-30, 6086 per serving, the maximum estimated daily intake (EDI) is 36.4 x 10^9 CFUs per day, which is significantly less than the ADI derived from the NOAEL from the 1-year chronic reproduction toxicology study described above.

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Conclusions and Expert Panel Signatures

V. Conclusions

Based on its independent and collective critical evaluation of the available information on GanedenBC^{30}™, the Expert Panel concludes that GanedenBC^{30}™, produced in accordance with current Good Manufacturing Practice, and meeting the specifications presented in the documents that are the basis for the GRAS determination, is safe at an acceptable daily intake of 9.38 x 10^{9} CFUs per day for its intended use. The Expert Panel further concludes that this use is GRAS based on scientific procedures and corroborated by a history of safe human use (exposure). The Expert Panel also believes that other qualified experts (qualified by training and/or experience to evaluate the safety of food ingredients) would concur with this GRAS conclusion. The results of the safety assessment were published with open in Food and Chemical Toxicology in February 2009 and thus have been freely available for 12 months. Publication of the 1-year study, which is the (b) (6) [redacted] nt, is pending.

Panel Mem (b) (6) [redacted]

STATE OF Florida
COUNTY OF Palm Beach
The foregoing instrument was acknowledged before me this 4-15
Theodore Farber who is personally known to me
who has produced ... as identification

(b) (6) [redacted] 4/15/10

Theodore Farber, PhD
Chair of Expert Panel

NOTARY PUBLIC STATE OF ...
My Commission Expires ... 11, 2013

(b) (6) [redacted] 4-17-10

Judith Hauswirth, PhD
Co-Chair of Expert Panel

(b) (6) [redacted]

Alexander G. Schauss, PhD, FACN
AIBMR Life Sciences, Inc
Expert Panel Member

LAURETTA ... NOTARY PUBLIC STATE OF WASHINGTON 11-26-1...

(b) (6) [redacted]

John R. Endres, ND
AIBMR Life Sciences, Inc.
Expert Panel Member

ALLAN J MANGUM NOTARY PUBLIC STATE OF WASHINGTON

County of ...
Subscribed and sworn/affirmed to before me this ___ day of ...

Notary Public
My Commission Expires 3/1/14

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Nutrition Insights

Consumption of Food Group Servings: People's Perceptions vs. Reality

INSIGHT 20 *A Publication of the USDA Center for Nutrition Policy and Promotion* **October 2000**

How accurate are people at remembering what they eat on an average day? Very accurate? Fairly accurate? Or just plain wrong? This *Nutrition Insight* helps answer those questions. We compared the average number of servings people estimate *usually* consuming on an average day from the five major food groups (grains; fruits; vegetables; milk products; and meat, poultry, fish, dry beans, eggs, and nuts) and fats, oils, and sweets with the average number of servings estimated from records of what they eat over a 14-day period.

We also compared "usual" and actual consumption with serving recommendations based on the USDA Food Guide Pyramid. The Pyramid translates nutritional recommendations from the *Dietary Guidelines for Americans* and the Recommended Dietary Allowances (RDAs) into the number of servings of the five major food groups a person should consume for a healthful diet. The Pyramid suggests servings for people with varying levels of caloric (energy) intake. With the exception of the milk products group, we set serving recommendations for six gender/age groups based on the energy RDA for each group.

We used data from Market Research Corporation of America (MRCA) Information Services. MRCA conducts a continuous sampling program by using a multistage stratified random design to identify participants for its National Consumer Panel. Households are selected based on demographic criteria matched to the U.S. Census.

For this *Insight*, we used information from 5,752 adults in these households for the 1992-94 period. This information includes their gender and age. It also includes their estimates or perceptions of usual daily servings consumed of grains; fruits; vegetables; milk products; meat, poultry, fish, dry beans, eggs, and nuts; and fats, oils, and sweets as well as their consumption from these food groups, based on detailed diaries of what foods were eaten over a 14-day period. However, portion sizes (quanti-

Food group servings: Perceived, average daily consumed, and recommended* by gender/age group

	Grains	Fruits	Vegetables	Milk	Meat, etc.	Other (fats, oils, and sweets)
Females 19-24						
Perceived	3.2	2.6	2.6	3.2	3.5	2.2
Consumed	4.2	0.8	1.7	1.2	1.6	3.0
Females 25-50						
Perceived	2.9	2.2	2.5	2.3	3.0	2.1
Consumed	4.6	0.8	2.0	1.0	1.7	3.2
Females 51 +						
Perceived	2.5	2.4	2.6	2.1	2.7	1.6
Consumed	4.7	1.5	2.2	1.0	1.7	3.1
Males19-24						
Perceived	2.9	2.1	2.2	3.1	3.7	2.1
Consumed	5.5	0.6	2.3	1.6	2.3	4.1
Males 25-50						
Perceived	2.9	2.2	2.4	2.2	3.4	2.1
Consumed	5.9	0.9	2.5	1.2	2.5	4.0
Males 51 +						
Perceived	2.7	2.2	2.5	2.1	3.1	1.7
Consumed	6.2	1.3	2.7	1.1	2.4	4.5

* *Recommended servings based on energy RDA for gender/age groups.*

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ties) eaten were estimated from data in National surveys of average serving sizes consumed by various gender/age groups.

For most food groups, the food servings in the MRCA data were estimated according to USDA Food Guide Pyramid recommendations. The exception was for milk products where MRCA serving measures were lower than Pyramid measures. Also, the amount of vegetables in vegetable chips, such as potato chips, was not added to vegetable consumption.

The Food Pyramid does not provide serving sizes or recommendations for fats, oils, and sweets. MRCA measured a serving of these foods as 1 teaspoon of butter or margarine, 12 ounces of carbonated soft drink, 1 teaspoon of sugar, 1 ounce of potato chips, 1 tablespoon of salad dressing, or 1 teaspoon of jam or jelly.

Grains

All gender/age groups perceived they consumed fewer grain servings (2.5 to 3.2) daily than what they actually ate (4.2 to 6.2) (table). Although all gender/age groups' actual consumption of grains per day was above what they believed, it was still below the Pyramid recommendations. For example, females ages 19 to 50 consumed 4.2 to 4.6 servings of grains per day: for them, the recommendation is 9 servings, based on their energy RDA.

Fruits

On average, each gender/age group perceived it consumed more fruit servings daily than what was actually the case. Males ages 19 to 50 believed they consumed 2.1 to 2.2 servings of fruit on a given day. Based on their food diaries, they actually consumed less than one serving per day. Since the recommendation for males ages 19 to 50 is 4 servings of fruit each day, based on their energy RDA, their actual daily consumption of fruit was below their perceptions as well as the recommendations. This held across all other gender/age groups–adults consume less fruit servings than they think and much less than is recommended.

Vegetables

Adult females perceived they consumed more vegetable servings per day than they actually consumed: 2.5 to 2.6 (perceived) versus 1.7 to 2.2 (actual). Adult males, on the other hand, believed they consumed slightly less vegetable servings per day than they actually consumed: 2.2 to 2.5 (perceived) versus 2.3 to 2.7 (actual). Both women's and men's daily vegetable consumption was below the recommendation for their respective gender/age group–3.5 to 5 servings a day.

Milk products

All gender/age groups perceived their usual daily milk servings to be far more than what they actually consumed. They thought they consumed, on average, 2.1 to 3.2 servings of milk products per day. Their food diaries indicated they consumed 1 to 1.6 servings per day. For most groups, what they actually consumed of milk products was about half the amount they thought they consumed.

Milk consumption per day was also below Pyramid recommendations for all gender/age groups. Given that the MRCA serving measures for milk are below the Pyramid measures, actual milk consumption per day is even further below Pyramid recommendations.

Meat

All gender/age groups perceived their usual servings of daily meat, poultry, fish, dry beans, eggs, and nuts to be more than what they actually consumed. They thought they consumed 2.7 to 3.7 servings, but their food diaries indicated they consumed 1.6 to 2.5 servings per day. Meat consumption per day was below Pyramid recommendations. For example, females ages 19 to 50 consumed 1.6 to 1.7 servings of meat per day; the recommendation for this group is 2.4.

Other foods (fats, oils, and sweets)

Each gender/age group perceived its average daily servings of fats, oils, and sweets to be far less than what was actually consumed: 1.6 to 2.2 (perceived) versus 3.0 to 4.5 (actual). The Food Guide Pyramid does not specify the number or size of servings of these other foods a person should consume. It only recommends that people consume these foods sparingly. Based on this analysis, it does not appear that people are consuming these foods sparingly.

Conclusion

People's perceptions of their food group consumption are very different from their actual consumption, based on diaries. Adults underestimated their consumption of servings of grains, as well as servings of fats, oils, and sweets. They overestimated their consumption of fruit, milk products, and meat, poultry, fish, dry beans, eggs, and nuts servings. The only exception was for vegetable servings by males. The difference between what people thought they ate and the number of servings they consumed may be the result of their not understanding what constitutes a serving. Nutrition education needs to focus on explaining to people what constitutes a serving for the various food groups and how to estimate the number of servings they eat.

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For more information, call the CNPP Office of Public Information and Governmental Affairs at (202) 418-2312.

Nutrition Insights is issued by the Center for Nutrition Policy and Promotion, an organization of the U.S. Department of Agriculture. **Nutrition Insights** may be accessed at the CNPP Web Site at http://www.usda.gov/cnpp.

The mission of the Center for Nutrition Policy and Promotion is to improve the health of Americans by developing and promoting dietary guidance that links scientific research to the nutrition needs of consumers.

SUBMISSION END